

**Summary Minutes of the
Tobacco Products Scientific Advisory Committee
August 30, 2010**

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd, Rockville, MD

All external requests for the meeting transcripts should be submitted to the CTP, Freedom of Information office.

These summary minutes for August 30, 2010 Meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on November 10, 2010.

I certify that I attended the August 30, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

**_____/s/_____
Cristi Stark, M.S.
Acting, Designated Federal Official, TPSAC**

**_____/s/_____
Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC**

Meeting of the Tobacco Products Scientific Advisory Committee August 30, 2010

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on August 30, 2010 at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd, Rockville, MD. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Cristi Stark, M.S. (Acting, Designated Federal Official). There were approximately 100 persons in attendance. There were 6 speakers for the Open Public Hearing session.

Issue: On August 30, 2010, the committee will receive a report from the Tobacco Product Constituents Subcommittee and discuss a proposed initial list of harmful or potentially harmful constituents, the rationale for inclusion of each constituent, established analytical methods as well as the ancillary methods and normalization standards for the identified constituents.

Attendance:

August 30, 2010:

Tobacco Products Scientific Advisory Committee Members Present (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H.
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)

Industry Representative Members Present (Non-voting):

Luby Arnold Hamm (Tobacco Growers Representative)
Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)
John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

Ex Officio Members Present (Non-Voting):

Ursula Bauer, Ph.D., M.P.H. (CDC)
Cathy Backinger, Ph.D., M.P.H. (NIH)
H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA)
Susan Karol, M.D. (IHS)

Consultant (Non-Voting) :

Stephen Hecht, Ph.D.

FDA Participants (Non-Voting):

David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

Acting, Designated Federal Official:

Cristi Stark, M.S.

Open Public Hearing Speakers:

David Johnson, Council of Independent Tobacco Manufacturers of America (CITMA)

Jim Tozzi, Center for Regulatory Effectiveness (CRE)

Jane Lewis, Altria Client Services

Ronald Tully, National Tobacco Company

Richard Higby, Arista Laboratories

Gregory Connolly, Harvard School of Medicine

The agenda was as follows:

August 30, 2010

Call to Order and Introductions

Jonathan Samet, M.D., M.S.

Committee Chair

Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement

Cristi Stark, M.S.

Acting, Designated Federal Official

Tobacco Products Scientific Advisory Committee

=====

FDA Presentation

Harmful/Potentially Harmful
Constituents in Tobacco Products
and Tobacco Smoke

Corinne Husten, M.D., M.P.H.

Senior Medical Advisor, CTP, FDA

Questions to the Presenters

**Recommendations from the
Tobacco Product Constituents
Subcommittee**

Stephen Hecht, Ph.D.

University of Minnesota

Questions to Presenters

Open Public Hearing

TPSAC Discussion

Questions to the TPSAC Committee
and TPSAC Vote

Closing Remarks

Adjourn

The session adjourned @ approximately 12:19 p.m.

Questions to the committee:

1. For carcinogens, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):

- Identified as a known or probable human carcinogen by either IARC, EPA, or NTP
This would include the following categories
 - IARC Group 1 and Group 2A (Sufficient evidence in humans or sufficient evidence in animals and strong mechanistic data in humans; limited evidence in humans and sufficient evidence in animals)
 - EPA – “known human carcinogen,” “likely human carcinogen” or “probable human carcinogen”
 - NTP – “human carcinogen,” “reasonably anticipated to be a human carcinogen”

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

2. For carcinogens, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No)

- Identified as possible human carcinogen by IARC or EPA; identified by NIOSH as a potential occupational carcinogen
This would include
 - IARC Group 2B – limited evidence in humans and less than sufficient evidence in animals
 - EPA – “possible human carcinogen”

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

3. For adverse respiratory or cardiac effects, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):

- Identified by EPA or ATSDR as having adverse respiratory or cardiac effects

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

4. For reproductive or developmental toxicants, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No)

- Identified by the California EPA as a reproductive or developmental toxicant

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

5. For chemical or chemical compounds with potential abuse liability, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No)

- Based on peer-reviewed literature, evidence of at least two of the following:

- Central Nervous System activity
- Animal drug discrimination
- Conditioned place preference
- Animal self-administration
- Human self-administration
- Drug “liking”
- Withdrawal

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

6. For smokeless tobacco products, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No)

Committee Vote:

- **Yes = 6**
- **No = 0**
- **Abstain = 0**

7. Do you recommend the following smoking machine regimens be used when measuring HPHC? (Vote Yes/No)

- Both ISO and Canadian Intense Methods

Committee Vote:

- **Yes = 4**
- **No = 1**
- **Abstain = 1**

IARC = International Agency for Research on Cancer

EPA = Environmental Protection Agency

NTP = National Toxicology Program

Please see the transcript for detailed discussion.